K024188

FEB 04 2003

510(k) Summary
for
Sony UP-DF500 FilmStation™ Digital Film Imager

1. Sponsor

Sony Medical Systems Division
Sony Electronics Inc.
1 Sony Drive
Park Ridge, NJ 07656

Contact Person: Mr. Anthony John Kefalos
Phone Number: 201-358-4330

Date Prepared: December 18, 2002

2. Device Name

Proprietary Name: UP-DF500 FilmStation™ Digital Film Imager
Common/Usual Name: Thermal Printer/Imager
Classification Name: Medical Image Hardcopy Device

3. Predicate Devices

- Agfa Drystar 4500 Printer
  Agfa Medical Imaging
  K010275

- Codonics Horizon Series Medical Multimedia Dry Imagers
  Codonics, Inc.
  K021054

- Fuji Medical Dry Imager FM-DP 2636
  Fuji Medical Systems USA, Inc.
  K962967

- KODAK DRY VIEW 8610 Laser Imager
  Eastman Kodak Company
  K002146

4. Device Description

The Sony UP-DF500 FilmStation™ Digital Film Imager is a general purpose thermal printer and is intended for use as an accessory to a wide variety of medical imaging systems for digitally printing black and white still images with DICOM format. The Sony UP-DF500 is connected to a DICOM network and the image from a compatible medical imaging system is transmitted via the DICOM network.

5. Intended Use

The Sony UP-DF500 FilmStation™ Digital Film Imager is a thermal printer intended for use in printing high-resolution diagnostic images from CT, MRI or other compatible medical imaging systems. The Sony UP-DF500 is intended for use by medical radiologists or other appropriately trained medical personnel.

6. Technological Characteristics and Substantial Equivalence

The Sony UP-DF500 FilmStation™ Digital Film Imager has the same overall purpose and function as the predicate devices cited above. All of the systems are intended to print a high-resolution, hard copy of an image generated by a medical imaging system. The printed images can be used for medical diagnostic purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2003

Sony Electronics, Inc.
% Cynthia A. Sinclair, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K024188
Trade/Device Name: Sony UP-DF500 FilmStation™ Digital Film Imager
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: December 18, 2002
Received: December 19, 2002

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K02 4188

Device Name: Sony UP-DF500 FilmStation™ Digital Film Imager

Indications for Use:

The Sony UP-DF500 FilmStation™ Digital Film Imager is a thermal printer intended for use in printing high-resolution diagnostic images from CT, MRI or other compatible medical imaging systems. The Sony UP-DF500 is intended for use by medical radiologists or other appropriately trained medical personnel.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K024188

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)